

Remarks

Claims 1-18 are pending and are under examination. Claims 19 and 20 have been added herein. The new claims do not introduce new subject matter and are fully supported by the specification and claims as filed.

Applicant points out that Examiner does not address or ascertain the level of ordinary skill in the pertinent art as required under MPEP 2141.

Examiner has withdrawn the previous obviousness rejection.

Independent claims 1 and 9 have been amended herein by incorporation of subject from claims 2 and 10, which have in turn been cancelled herein, without prejudice to the inclusion of their subject matter in a continuing application. No new subject matter has been introduced by way of these amendments, which are fully supported by the specification and claims as filed.

Response to Rejection of Claims 1-18 under 103(a), obviousness

The Examiner has rejected claims 1-18 as allegedly obvious over Reillo et al. (J. Assoc. Nurses in AIDS, Jan-Feb. 1996 in view of Risley (U.S. Patent No. 7,198,045).

Examiner asserts that Reillo discloses hyperbaric oxygenation for HIV treatment decreasing the viral load, which would inherently increase the CD4/CD8 lymphocytes. The Examiner then asserts that "it is obvious that one or more gases is used to treat the HIV in a hyperbaric chamber".

It is the opinion of the Examiner that the difference between Reillo and claim 1 is the selecting of one or more time periods for exposing the patient to the selected gas(es) and pressure. The Examiner then states that Risley teaches time periods selected for patients in a hyperbaric chamber (citing Col. 4, lines 48-57).

Based on the assertions described above, it is the view of the Examiner that it would have been obvious to select time periods for the user as taught by Risley and that it would have been obvious that no set time period or gas pressure for everyone would work the same, as different people have different needs, such as a younger person may need less or more time in treatment, an older person may require less time in treatment to receive the same effects as the younger person. The Examiner also asserts that a health care provider would take each patient and evaluate their needs to set up a treatment schedule for time and pressure in the chamber. The

Examiner then reasons that the remaining steps of claim 1 would have been obvious “because they would have resulted from the use of the hyperbaric chamber of Reillo/ Risley”.

As to claim 2, Examiner admits that Reillo/Risley do not disclose the claimed one or more gases. However, in the view of the Examiner, it would have been an obvious design consideration to one of ordinary skill in the art to have one or more of the gases to be nitrogen, surface air, an inert gas, nitrous oxide, or another anesthetic and wherein one or more except air make up 5% or more of the gases in the chamber, asserting that “because the gases are all known in the respiratory art and would have been based on individual user needs and problem being treated”.

Regarding claim 3, Examiner admits that Reillo does not specifically state that selected pressures are one or more atmospheres. However, the Examiner asserts that “it would be inherent that the pressure would be greater than one atmosphere because the device is a hyperbaric chamber.

Regarding claims 4-6, the Examiner states “note rejections of claim 1”.

Regarding claim 7, the Examiner admits that Reillo does not disclose the step of creating a chart for the person with listing of times and gas based upon the patient’s condition. The Examiner then asserts that one of ordinary skill in the art would consider the step obvious if not inherent.

Regarding claim 8, Examiner asserts that Risley teaches a hyperbaric chamber large enough for more than one person and that it would have been obvious to have more than one person in a chamber as recited in claim 8.

Regarding “independent” claim 9, the Examiner states “note rejection of claim 1”.

Regarding claim 10, the Examiner refers to the rejection of claim 1 and asserts that it would have been obvious to “arrive at the percentage of gases in the chamber based upon how many patients are in the chamber and their medical conditions requiring treatment”.

Regarding claim 11, the Examiner states “note rejection of claim 1”.

Regarding claim 12, the Examiner does not mention claim 12, but does mention claim 13 twice in a row. Applicant assumes that Examiner was intending to recite claim 12 at the first instance where she mentions claim 13. Applicant will address accordingly below. However, at the first instance of citing claim 13, Examiner states “note rejection of claim 1”.

Regarding claim 13, the Examiner states “note rejection of claim 8”.

Regarding claim 14, the Examiner asserts that the step is inherent that a person must decompress based upon standard decompression tables because decompression is needed to prevent a patient from becoming ill in the chamber after being at a selected pressure for an extended period of time.

Regarding independent claim 15, and its dependent claims 16-18, the Examiner states “note rejections of claims 1 and 10”.

Applicant traverses the rejection for reasons described below and asserts that based upon the claim amendments herein and on the arguments provided herein, the claims as amended, as well as the newly added claims, are in condition for allowance.

Pertinent Law

Preliminarily, the three-prong test which must be met for a reference or a combination of references to establish a *prima facie* case of obviousness has not been satisfied in the instant matter. The MPEP states, in relevant part:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. MPEP § 2142.

Additionally, MPEP § 2143.01 provides: “The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).” However, the “teaching, suggestion, motivation” test (“TSM”) must not be rigidly applied (*KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007)), but to determine **whether there is an apparent reason to combine the known elements in the fashion as claimed, the analysis should be made explicit by the Examiner** (*Id.*) (emphasis added)

The Examiner has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir.1988). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested, by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) ; MPEP §

2143.03. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970) ; MPEP § 2143.03. As part of establishing a *prima facie* case of obviousness, the Examiner's analysis must show that some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art would lead an individual to combine the relevant teaching of the references. *Id.* The court in *Fine* stated that:

Obviousness is tested by "what the combined teaching of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 878 (CCPA 1981)). But it "cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *ACS Hosp. Sys.*, 732 F.2d at 1577, 221 USPQ at 933. And "teachings of references can be combined *only* if there is some suggestion or incentive to do so." *Id.* (emphasis in original).

The test for obviousness under §103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir.1985). The Examiner must, as one of the inquiries pertinent to any obviousness inquiry under 35 U.S.C. §103, recognize and consider not only the similarities but also the critical differences between the claimed invention and the prior art. *In re Bond*, 910 F.2d 831, 834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990), *reh'g denied*, 1990 U.S. App. LEXIS 19971 (Fed. Cir.1990). The fact that a reference teaches away from a claimed invention is highly probative that the reference would not have rendered the claimed invention obvious to one of ordinary skill in the art. *Stranco Inc. v. Atlantes Chemical Systems, Inc.*, 15 USPQ2d 1704, 1713 (Tex. 1990). When the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious. *KSR Int'l Co.*, 550 U.S. ____ (2007)(slip opinion at 12)(citing *United States v. Adams*, 383 U.S. 39, 51-51 (1966)).

Further, the Office Action must provide specific, objective evidence of record for a finding of a suggestion or motivation to combine reference teachings and must explain the reasoning by which the evidence is deemed to support such a finding. *See KSR Int'l Co.*, 550 U.S. ____ (2007)(slip opinion at 14)(citing *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006)); *In re Sang Su Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002), and more recently in *Ex parte*

Wada and Murphy (BPAI Appeal No. 2007-3733, 1/14/08). Conclusions of obviousness must be based on facts, not generality. *In re Warner*, 379 F.2d 1011, 1017 (C.C.P.A. 1967); *In re Freed*, 425 F.2d 785, 787 (C.C.P.A. 1970). Additionally, an Examiner must specifically articulate a sufficient reason why one skilled in the art would have modified the art and arrived at the presently claimed subject matter. *Ex parte Penhasi*, BPAI Appeal No. 2007-2534 (12/13/07).

The requirement of objective evidence in an obviousness rejection has been further supported by recent decisions of the Board of Patent Appeals and Interferences. For example, in *Ex parte Rathman*, BPAI Appeal No. 2007-4156, 12/11/07, the Board stated that the mere recognition that “[t]he genetic modification of cells has been routine in the art for some 20+ years. . . does not mean that a person of ordinary skill in the art would willy-nilly modify any cell with any gene to treat a disease”. The Board in *Ex parte Rathman* also noted that “the inferences and creative steps derived from the prior art on this record fail to lead a person of ordinary skill in the art to Appellants’ claimed invention”. The Board then asserted that the **Examiner must identify a viable reason** why a person of ordinary skill would have been led to combine the teachings of the cited art in the manner set forth by the Appellants’ claimed invention. Finally, the Examiner must avoid hindsight. *In re Bond* at 834. (emphasis added)

Additionally, MPEP 2143.02 requires that there be **at least some degree of predictability for there to be a reasonable expectation of success** (*In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) (emphasis added)). More recently, the Board held that optimization of a known result-effective variable in a given range is **obvious “only” when it is reasonably expected that an improvement will arise in that range** (*Ex Parte Atkinson and Benedict*, BPAI Appeal No. 2007-3900, 12/18/07, citing *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003) and *In re Aller*, 220 F.2d 454, 456 (CCPA 1955)) (emphasis added). That predictability must be determined at the time the invention was made (*Ex parte Erlich*, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986).

None of these criteria have been met here.

Claim Amendments

First, although not necessarily agreeing with the reasoning of the Examiner, the claims have been amended herein to more specifically and clearly recite that subject matter which is encompassed by the invention.

Claims 1 and 9 have been amended in a similar manner. That is, claim 1, drawn to a method of “increasing a ratio of CD4/CD8 lymphocytes... to treat a viral infection using a hyperbaric chamber and a mixture of gases” has been amended by incorporating the subject matter of its dependent claim 2, and further stipulating that at least one of the one or more gases must be nitrogen or nitrous oxide. Claim 9, drawn to a method of preventing reproduction of a virus using a pressurized chamber with gases, wherein said method causes an atom to competitively inhibit a virus from attaching to a cell or receptor, has been amended similarly to claim 1. Claim 2, which depended from claim 1, and claim 10, which depended from claim 9, have been canceled herein. New claims 19 and 20, which depend from independent claims 1 and 9, respectively, have been added and specifically recite the use of a pressure of normal atmospheric pressure. The addition of these two claims is specifically supported by the claims from which they depend. No new subject matter has been introduced by way of these amendments and these amendments are supported throughout the specification as filed, particularly by the claims as filed.

Reillo in view of Risley does **not** render claims 1-18 obvious

First, Applicant will provide arguments as to why, even assuming *arguendo* that either reference could be cited as prior art, the two references, alone or together, do not render the present claims obvious. Second, Applicant will demonstrate that the Risley reference is not valid prior art against the present application. Although Applicant asserts in a separate section below that the combination of Reillo and Risley is improper because Risley does not properly qualify as prior art to the present application, Applicant addresses the two references here as if, presuming *arguendo*, they did qualify as proper prior art.

Claims 2 and 10 have been canceled herein, therefore the rejection as to these claims is now moot. Applicant requests that the rejection as to these claims be withdrawn.

Claims 19 (which depends from claim 1) and 20 (which depends from claim 9) have been added herein. Applicant submits that the discussion herein as to the allowability of claims 1-18, applies to claims 19 and 20 as well.

Applicant also asserts that the only commonality between Reillo and Risley is the use of a hyperbaric chamber, and that their fields of use were entirely different. Applicant asserts that the field of treating HIV, as in Reillo, and the field of managing pain, as in Risley, are not similar

fields and that there is no basis for one of ordinary skill in the art to relate treating HIV to treating pain, thus there would have been no reason to combine the references, and in fact one of ordinary skill in the art of one field would not look to the other field.

Applicant notes that the Examiner does not address or ascertain the level of ordinary skill in the pertinent art as required under MPEP 2141 and requests that any further actions do so.

Applicant will address all three independent claims (1, 9, and 15) and their dependent claims, and specifically point out how the claims differ in specific elements recited. Applicant is doing so as a reminder that all claims do not stand or fall together and that the Examiner is required to establish a prima facie case of obviousness for each and every independent claim, as well as each and every dependent claim (see *Ex parte Cohen*, BPAI Appeal 2007-4368, 12/31/07).

Regarding the rejection of “independent” claim 1, Applicant points out that each and every element of claim must be taught or suggested by the prior art, and Applicant asserts that these references do not. Contrary to the assertion of the Examiner, neither Reillo nor Risley teach, suggest, or even contemplate each and every element of independent claim 1, as amended, and its dependent claims 2-8. That is, they do not conform to the multiple criteria recited above for making an obviousness rejection. Additionally, Applicant asserts that in several instances the Examiner makes assertions regarding knowledge in the art, but does not cite such art to substantiate the assertion. Applicant submits that such documentation is required and requests that if another Office Action is rendered that it contain references to support assertions of what is known in the art.

The present application is the first to disclose that the use of an inhaled nitrogen or other nitrogen containing gas is effective in treating viral infection, and is in fact much more effective than the use of hyperbaric oxygenation alone. Claim 1, as amended, recites:

1. (Currently Amended) A method for increasing a ratio of CD4/CD8 lymphocytes, reducing a viral load and restoring an immune system, including lymph node architecture, of a person infected with at least one virus, such as HIV, wherein the person is placed in a hyperbaric chamber and exposed to one or more gases at one or more atmospheric pressures for one or more time-periods, wherein the one or more gases is nitrogen, surface air, an inert gas, nitrous oxide or another anesthetic, and wherein the one or more gases, except for air, make up 5% or more of gases in the chamber, further wherein at least one of the one or more gases is nitrogen or nitrous oxide, the method comprising the steps of:

selecting the one or more gases to be used in the hyperbaric chamber;

selecting the one or more pressures to be used in the hyperbaric chamber;
selecting the one or more time-periods that the patient is exposed to the selected gas(es) and pressure(s) while in the hyperbaric chamber;
placing the patient in, or having the patient enter, the hyperbaric chamber wherein monitoring of the patient's vital signs may optionally be provided; and,
exposing the patient to the selected one or more gases, at the selected one or more pressures for the selected one or more time-periods.

The Examiner, at page 2, asserts that the difference between Reillo and claim 1 is the selecting of one or more time periods for exposing the patient to the selected gas(es) and pressure. Applicant asserts this is not the only difference and that Reillo does not teach or suggest all of the elements of claim 1 as amended or its dependent claims as asserted by the Examiner, nor does Reillo or Risley teach each and every element of claim 1.

An extremely important difference between Reillo, as well as Reillo and Risley, and the present claims, is the use of gases other than oxygen, including nitrogen containing gases and that the other gases comprise at least 5% of the gases in the chamber. In fact, Examiner admits at page 3 regarding claim 2 (the subject matter of which has now been incorporated into amended claim 1), that Reillo/Risley do not disclose the claimed one or more gases. However, the Examiner goes on to assert that it would have been an obvious design consideration to one of skill in the art to use the recited elements, now incorporated into claim 1. That is "wherein the one or more gases is nitrogen, surface air, an inert gas, nitrous oxide or another anesthetic, and wherein the one or more gases, except for air, make up 5% or more of gases in the chamber, further wherein at least one of the one or more gases is nitrogen or nitrous oxide". Applicant submits that the real question regarding obviousness should be "would one of ordinary skill in the art want to, or be motivated to modify or combine the HIV treatment of Reillo, which appears to successfully use hyperbaric oxygenation (and no other gases), with the pain treatment of Reillo which appears to successfully use hyperbaric oxygenation (and no other gases), to arrive at the present invention which uses, inter alia, nitrogen gases which were found by the Applicant to be unexpectedly more effective than oxygen alone?". This question does not even contemplate the additional elements recited in claim 1 that are not taught or suggested by Reillo/Risley. However, when referring to the important recitation of the use of nitrogen and nitrous oxide as recited in amended claim 1, these references do not teach, suggest, or even contemplate its use, nor would there have been a reasonable or predictable expectation of success

as is required by law (MPEP 2143.02; *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976; *Ex parte Atkinson and Benedict*, BPAI Appeal No. 2007-3900, 12/18/07; *Ex parte Rathman*, BPAI Appeal No. 2007-4156, 12/11/07). Furthermore, the Examiner provides no objective evidence to support the assertion that it would be obvious to use other gases, the nitrogen ones in particular, as is required. (*KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007); *Ex parte Penhasi*, BPAI Appeal No. 2007-2534 (12/13/07); *Ex parte Wada and Murphy*, BPAI Appeal No. 2007-3733, 1/14/08). There was nothing in those references, or any other art to which the Examiner may have been trying to take notice of, which suggests that using a different gas such as nitrogen or nitrous oxide, as is recited in the present claims, would be effective, much less more effective than hyperbaric oxygenation. Even if the references were combined, the result is not the present invention.

Another difference between Reillo and Risley and what is presently claimed is that Reillo only teaches treating HIV, while Risley only teaches treating pain. They do not teach or suggest treating other viruses, as is recited in claim 1, as well as in independent claims 9 and 15. Additionally, Reillo is not an enabling reference even if it did suggest treating other viruses, as is taught and claimed in the present application.

Furthermore, the data provided in the present application point to a different conclusion than that forwarded by the Examiner regarding obviousness. For example, the data demonstrate that nitrogen not only worked, but that it was much more effective than hyperbaric oxygenation in treating virus. For example, one element recited by claim 1 is “restoring lymph node architecture”, which is not taught or suggested by Reillo or Risley. It can be seen in Figure 5B that nitrogen treatment was very effective in restoring lymph node architecture. The data from these experiments is also provided in graphic form in Figure 6. There it can be seen that, not only is nitrogen effective, it is much more effective than hyperbaric oxygenation (see also paragraphs 0051 to 0054 of this application as published- US 2005/0056285).

Examiner refers to viral load data of Reillo, and then makes an unsupported statement that this would inherently increase the ratio of CD4/CD8 lymphocytes, which is an element recited in current claim 1. Applicant submits that this statement by the Examiner regarding “inherently increasing the ratio of CD4/CD8 lymphocytes” should be withdrawn unless art is cited to support it as is required for an obviousness rejection.

Additionally, Applicant points out that claim 1 as amended not only recites “increasing a ratio of CD4/CD8 lymphocytes” and “reducing a viral load”, which the Examiner asserts is taught by Reillo, claim 1 also recites “restoring an immune system, including lymph node architecture”, which are not taught or suggested by the art, particularly not Reillo or Risley. The Examiner did not address this aspect of the claim at all. Regardless, neither Reillo nor Risley teach or suggest “restoring an immune system, including lymph node architecture”, therefore, they do not render this element of claim 1 obvious, and therefore cannot render claim 1 obvious.

Furthermore, amended claim 1 also encompasses providing the gases independently of the pressure, neither of which are contemplated or suggested by Reillo or Risley. For example, dependent claim 3 recites that the pressure is greater than one atmosphere, which means that the pressure of claim 1 could be atmospheric pressure, which is not taught or suggested by Reillo or Risley, nor does the combination of the two teach or suggest treating a patient at one atmosphere, as is recited in claim 1. Applicant points out that the Examiner did not provide a rationale, reasoning, or objective evidence as to why Reillo or Risley teach or suggest varying the pressure, wherein the pressure can be a range and does not have to be greater than one atmosphere, as recited in claim 1.

Regarding Risley, it in fact merely teaches the use of a hyperbaric chamber for treatment of pain using low pressure (see abstract) and there would be no motivation or reason to combine a method for treating pain, as in Risley with one for treating a disease, as in Reillo, much less a reasonable or predictable expectation of success. Risley does not teach, suggest or contemplate any of these elements: a method for increasing a ratio of CD4/CD8 lymphocytes; reducing a viral load and restoring an immune system; including lymph node architecture; of a person infected with at least one virus; such as HIV, as recited in claim 1; use of a pressurized chamber to cause an atom, molecule or compound into an attachment site on a cell wall of a living cell or into a receptor unit on the virus, whereby the atom, molecule, or compound prevents the virus from replicating by preventing the virus from attaching to the attachment of the living cell or receptor, as recited in claim 9; or the use of nitrous oxide inhalation at normal atmospheric pressure for blocking virus attachment to host cells and preventing virus replication in a host; as recited in independent claim 15. Furthermore, the low pressure taught by Risley (less than 32.0 inches of Hg, is only slightly higher than about 1 atm (1 atm = 760 mm Hg = 29.9 in. Hg), while claims 1 and 9 and their dependent claims recite the use of a range of pressures, including one

atmosphere. Claim 15 and its dependent claims do **not** even recite the use of a hyperbaric chamber or increased pressure using a hyperbaric chamber. Therefore, there would no reason or motivation to combine Risley with Reillo or a reasonable or predictable expectation of success as to arriving at claim 1, much less claims 1-18, as well as newly added claims 19 and 20, because they teach different amounts of pressure than the claims as recited and do not suggest that nitrogen or other gases could be used, much less that they would work better than oxygen, as used and taught by Reillo and Risley. There would be no motivation to vary the pressure as asserted by the Examiner, because both Reillo and Risley were successful in their results and neither suggested that varying pressure would perhaps provide better results.

Regarding the rejection of claim 2, the bulk of the subject matter has been incorporated into claim 1, and claim 2 has been canceled herein.

Regarding the rejection of claim 3, Applicant asserts that the arguments provided for amended claim 1 apply with equal force here. Examiner admits that Reillo does not specifically state wherein one or more pressures selected is greater than one atmosphere as is recited in claim 3, but asserts it would be inherent that the pressure would be greater than one atmosphere because the device is a hyperbaric chamber. Applicants traverse this rejection, noting that in addition to not addressing varying pressures, Reillo does not teach or address the elements of claim 1 discussed above, from which claim 3 depends. Additionally, the Examiner must do more than merely state that something is "inherent" for use in an obviousness rejection. The examiner must provide evidence that one of ordinary skill in the art would have varied the pressure at ranges greater than one atmosphere and articulate a sufficient reason as to why one skilled in the art would have modified the art and arrived at the presently claimed subject matter (Ex Parte Penhasi; *Ex parte So and Thomas*, BPAI, 2007-3967; January 4, 2008). A hyperbaric chamber does not have to necessarily be used under pressure and can be used as a means to regulate the air and gases which a patient is exposed to. For example, new dependent claims 19 and 20 (discussed further below) recite "one atmosphere" of pressure, and independent claims 1 and 9 encompass such a recitation. The method can be performed in a hyperbaric chamber to control the gases, timing, etc., but a chamber is not specifically recited in that claim because only "one atmosphere" of pressure is being recited and the method can be performed without a hyperbaric chamber. Applicant also points out that, as discussed in detail below, claim 15 does not recite

the use of a chamber at all, and in fact only recites inhalation of nitrous oxide at normal atmospheric pressure.

In fact, based on their data and discussions both references would suggest that pressure is needed based on the fact that they studying and using only hyperbaric oxygen, had success with oxygen under pressure, did not discuss other pressures or gases, which in fact would teach away from using only one atmospheric pressure as claimed herein, as well as teach away from using other gases. Therefore, neither Reillo nor Risley, teach or suggest each and every limitation of claim 15 and its dependent claims. Furthermore, even if they did, they provided no motivation or suggestion to modify or combine the references to arrive at the present invention, nor was there a predictable or reasonable expectation of success. In fact, even if the teachings of Reillo and Risley were combined, they do not result in the present invention as recited in claims 15-18.

Regarding the Examiner's comments about "health care providers" as recited on page 3, or "medical person" as recited on page 3, or "inherent" as recited on pages 3 and 4 of the Office Action, Applicant asserts that the Examiner provides no evidence that health care providers/medical person would have known or done what the Examiner speculates they would have done regarding manipulations (as related to using nitrous oxide at normal atmospheric pressure), nor evidence of inherent indications for use, and that the Examiner should provide evidence of such to indicate that Examiner is not using impermissible hindsight or taking notice to arrive at such a conclusion. For example, the Examiner states that as to claim 3, it would be "inherent" to increase pressure because it is a hyperbaric chamber. However, applicant notes that the cited references using a hyperbaric chamber were not using variable pressures, therefore it would not have been inherent to do so, and thus, it would not have even been obvious to do so. Applicant further notes that the mere fact that a hyperbaric chamber is being used does not mean that there must be pressure as well.

Presuming arguendo that the references show the elements or concepts urged by the examiner, the examiner has presented no line of reasoning, and we know of none, as to why the artisan viewing only the collective teachings of the references would have found it obvious to selectively pick and choose various elements and/or concepts from the several references relied upon to arrive at the claimed invention. *Ex Parte Clapp*, 227 USPQ 972 (PTO Bd App. 1985); *In Re Horn*, 203 USPQ 969 (CCPA 1979). More recently the Board held that, regarding hindsight analysis in an obviousness rejection "there is nothing in the applied references which

would have motivated an artisan to select the particular ingredient and then use the resulting composition” (*Ex parte So and Thomas*, BPAI, 2007-3967; January 4, 2008). The collection of references cited by the Examiner supports the inescapable conclusion that the Examiner has pieced the references together to support a rejection on the basis of hindsight.

As the Federal Circuit has held numerous times, such a hindsight analysis is impermissible -- instead, the Examiner must show suggestions, explicit or otherwise, that would compel one of ordinary skill to combine the cited references in order to make and use the claimed invention. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 (Fed. Cir. 1985) (“When prior art references require selective combination by the [fact-finder] to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself.”); *Fine*, 5 USPQ2d at 1600 (“One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.”); *In re Pleuddemann*, 910 F.2d 823, 828 (Fed. Cir. 1990) (noting that use of an applicant’s specification as though it were prior art to support an obviousness determination is legal error); *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991) (holding that both the suggestion to combine references, and a reasonable expectation of success in making the claimed invention, “must be founded in the prior art, not in the applicant’s disclosure.”). The Board has also provided the same mandate on this issue:

"it is impermissible to use the claimed invention as an instruction manual or “template” to piece together isolated disclosures and teachings of the prior art so that the claimed invention may be rendered obvious a rejection based on § 103 must rest on a factual basis, with the facts being interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, the examiner has the initial duty of supplying the factual basis for the rejection he advances. He may not, because he doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis."

Ex parte Haymond, 41 USPQ2d 1217, 1220 (Bd. Pat. App. Int. 1996). Thus, the use of hindsight analysis in the present case is impermissible and cannot be used to attempt to establish a *prima facie* case of obviousness.

Regarding the rejection of claims 4-6, which depend from claim 1, the Examiner referred to independent claim 1 for the reasoning of the rejection. Applicant submits that the arguments

provided above apply with equal force here, and that based on those arguments and those provided here specifically for claims 4-6 the claims are allowable.

Regarding the rejection of claim 5, Applicant points out that the pressures recited in the claim, namely “an underwater pressure of between 70 and 165 feet” were discovered by the Applicant as useful and relate to what is described in the present application regarding divers and the pressures to which they are submitted when diving, and in fact led to the current invention. The pressures recited in claim 5 relate to pressures are those experience experienced by divers, and these pressures are not taught, suggested, or even contemplated by Reillo or Risley, and there is nothing in either reference that would provide the motivation or suggest that diving pressure should be emulated, much less using gases other than oxygen, or nitrogen or nitrous oxide, as is encompassed by claim 5 as it depends from amended claim 1. Nor was there a reasonable expectation of success. This rejection as to claim 5 does not satisfy the requirements of *KSR v. Teleflex* or *Ex Parte Wada and Murphy*, BPAI Appeal No. 2007-3733 (1/14/08), nor does the Examiner specifically articulate a sufficient reason why one skilled in the art would have modified the art and arrived at the presently claimed subject matter as is required by *Ex parte Penhasi*, BPAI Appeal No. 2007-2534 (12/13/07). Therefore, claim 5 is not obvious over Reillo and Risley.

Regarding the rejection of dependent claim 7, the Examiner asserts that one of ordinary skill in the art would consider the step obvious if not inherent. Applicant asserts that based on the non-obviousness of amended claim 1, from which claim 7 depends, claim 7 is not obvious.

Regarding the rejection of claim 8, where the Examiner asserts that Risley teaches a hyperbaric chamber large enough for more than one person, Applicant asserts that claim 8 is not obvious over Reillo and Risley. First, the arguments supplied above for claim 1 and the other claims apply with equal force here. Additionally, as per the arguments provided in the last section of this response, Risley is improper prior art. Therefore, claim 8 is not obvious over Reillo and Risley.

Regarding the rejection of “independent” claim 9, Applicant asserts that the applicable arguments supplied above as to the rejection of claim 1 apply with equal force. The Examiner refers to the rejection of claim 1 as the sole reason for rejection of claim 9, but Applicant points out that totally different elements are recited in claim 9, relative to claim 1. The preamble of independent claim 9, as amended herein, recites:

A method for preventing reproduction of a virus wherein a pressurized chamber is used to cause an atom, molecule or compound from gases that fills the chamber, or from within a patient's body, into an attachment site on a cell wall of a living cell or into a receptor unit on the virus, whereby the atom, molecule or compound prevents the virus from replicating by preventing the virus from attaching to the attachment site of the living cell, the method comprising the steps of:
(emphasis added)

The remainder of amended independent claim 9 recites the steps of the process, the use of various gases, etc., as recited in claim 1.

Applicant points out that the elements underlined above in claim 9 are not taught or suggested by Reillo or Risley, and neither reference provides motivation for such, nor would there be a reasonable or predictable expectation of success, as is required for an obviousness rejection. Neither Reillo nor Risley teach, suggest, or even contemplate a method for causing atoms, molecules, or compounds to bind to attachment sites which a virus would normally attach to, thus preventing the virus from attaching, and ultimately preventing virus replication. They do not remotely contemplate regulating such a molecular pathway. Additionally, claim 9 recites the use of other gases, one of which must be nitrogen or nitrous oxide, which as discussed above in reference to claim 1 is not taught or suggested by Reillo and Risley. Because none of these elements of claim 9 are taught or suggested by Reillo and Risley, there would be no motivation to combine or modify the references, there would be no reasonable or predictable expectation of success, and in fact the combination of the references does not result in the invention of claim 9. Therefore, Applicant submits that claim 9 is not obvious over the combination of Reillo and Risley and requests that the rejection be withdrawn.

Regarding the rejection of dependent claim 10, it has been canceled herein and the rejection is now moot.

Regarding the rejection of dependent claims 11-14, Applicant submits that the arguments provided above as to claim 1 and its dependent claims apply with equal force here, as do the arguments for claim 9, from which claims 11-14 depend.

Regarding the rejection of claims 15-18, the Examiner refers to the rejections of claims 1 and 10 above. Contrary to the assertion of the Examiner, neither Reillo nor Risley teach, suggest, or even contemplate each and every element of independent claim 15 and its dependent

claims 16, 17, and 18. As admitted by the Examiner Reillo and Risley teach the use of hyperbaric chambers. Claims 15, 16, 17, and 18 do not recite the use of hyperbaric chambers.

Claim 15 recites:

15. A method for the treatment of patients infected with a virus, including HIV, involving the **inhalation of nitrous oxide at normal atmospheric pressure** wherein inhaled nitrogen blocks virus-host attachment sites and prevents the virus from replicating thereby reducing viral load and restoring a patient's immune system, the method comprising the steps of: selecting an inhalation period, wherein the patient inhales gases comprising nitrous oxide during the inhalation period; selecting a number of times to repeat the inhalation period; having the patient inhale the gases comprising nitrous oxide for the selected inhalation period and, repeating the step of having the patient inhale the gases for the selected number of times. (emphasis added)

Applicant notes that "independent" claim 15 is different than the other independent claims in that it does **not** specifically recite the use of a hyperbaric chamber, that it only recites the use of normal atmospheric pressure, and that it specifically recites the inhalation of nitrous oxide. Applicant submits that although the Examiner did not highlight this difference between claim 15, the other claims, and the Reillo and Risley references, and did not specifically comment on each and every element of claim 15 and its dependent claims, claim 15, as amended, and its dependent claims 16-18, are not obvious over Reillo and Risley for the following reasons.

Based on the assertions of the Examiner, and the success of Reillo, which only used hyperbaric oxygenation, there would have been no motivation to treat a patient with a virus by inhalation of nitrous oxide or any other additional gases as recited in claim 15, much less doing it at normal atmospheric pressure as recited in claim 15. As described above, Risley used only hyperbaric oxygen and only used it for treatment of pain. There would have been no motivation to combine it with Reillo, much less a reasonable expectation of success. Furthermore, even if Reillo and Risley were combined using their teachings, the resulting combination would not be the invention as recited in claim 1, and there would be no reasonable expectation of success, nor could there have been any predictability of such.

Accordingly, if the scope and content of the cited prior art are properly considered as set forth above, it becomes clear that the combination of the Reillo and the Risley patent do not lead the ordinary skilled artisan to Applicants' presently-claimed invention as set forth in claims 1-18, or newly added claims 19 and 20.

Risley is Improper Prior Art

Risley is not a proper prior art reference

Applicant asserts that Risley is not a prior art reference under the conditions set forth in 35 U.S.C. § 102 and therefore cannot be relied upon as a prior art reference under 35 U.S.C. § 103 for the reasons set forth below.

The present application has a priority date of March 23, 2001. Risley was filed Feb. 10, 2003, without benefit of priority of an earlier filed application. The present application under consideration was filed in the U.S. on September 12, 2003, and has the benefit of priority of PCT/US02/09416 filed on Monday, March 25, 2002 (March 23, being a Saturday), which has the benefit of priority of U.S. Provisional Patent Application No. 60/278,141, filed on **March 23, 2001**. Therefore, Risley cannot be cited against the present application because, not only does it not predate the provisional priority filing date of the present application, it does not even predate the PCT filing date of the present U.S. application. Therefore, Applicant respectfully submits that the use of Risley is not proper and requests that the Examiner withdraw the use of the Risley reference. Because Risley does not have a proper filing or priority date which qualifies as prior art under 35 U.S.C. § 102, it cannot be used in a 103 rejection and the rejection of Reillo in view of Risley fails for that reason.

Because Risley is not a proper prior art reference under 102, it cannot be cited against the present application in a 103 rejection. Furthermore, even if one of the two cited references were a proper prior art reference, the rejection would fail because the two references could not be combined according to the rejection issued by the Examiner. Thus, the rejection fails either way.

For these reasons, Applicant submits that the obviousness rejection as to amended claim 1, claims 3-8, claim 9 as amended, and claims 11-18, claims 2 and 10 having been cancelled herein, and insofar as it would apply to newly added claims 19 and 20, is improper and should be withdrawn. Applicant further submits that the claims as amended are in condition for allowance.

Conclusion

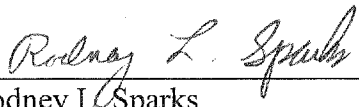
Applicant submits that the rejection fails for two reasons. The first is that the cited references do not render the claims obvious. The second is that Risley is not a proper prior art reference and therefore its use is not allowable and it should be withdrawn by the Examiner. Applicant requests that the 103 rejection as to Reillo and Risley be withdrawn as to amended

claim 1, claims 3-8, claim 9 as amended, and claims 11-18, claims 2 and 10 having been cancelled herein, and insofar as the rejection would apply to newly added claims 19 and 20, and submits that the claims as amended, as well as newly added claims 19 and 20, are in condition for allowance.

If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (434) 243-6103.

Respectfully submitted,

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